

REMARKS

5 This amendment is being filed in response to an Office Action mailed 10/26/2005, in which the Examiner said that claims 1-19 were pending, that claims 1, 3-8, 10-17, and 19 were rejected, and that claims 2, 9, and 18 were objected to. In this amendment, claims 1 and 7 are canceled, claims 2-6, 8-12 and 18 are amended to overcome the objections and rejections of the Examiner, and new claims 20-23 are added. Other reasons for rejections are traversed below.

10 **Claims Rejected under 35 USC §112**

15 In the above-mentioned Office Action, the Examiner said that claims 10-12 were rejected under 35 USC §112, second paragraph, because these claims recite the limitation "the lateral structure" or "the lateral blades," for which there is insufficient antecedent basis in claim 8, from which claims 10 and 12 depend, and which recites "second lateral structure."

20 In this amendment, claim 10 is amended to recite "the first lateral structure and the second lateral structure," for which antecedent basis is found in claim 9, from which claim 10 is amended to depend. Claims 11 and 12 are amended to recite "the first lateral blade and the second lateral blade," for which antecedent basis is found in claim 9, from which claims 11 and 12 are also amended to depend.

25 **Claims to which Objections were Made**

Regarding claims 2, 8, and 10, the Examiner further said that these claims were objected to as being dependent upon a rejected base claim, but that these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

30 In this amendment, this has been done, with claim 2 being rewritten to include all

of the limitations of claim 1, with claim 9 being rewritten to include all of the limitations of claim 1, with claim 9 being rewritten to include all of the limitations of claim 8, and with claim 18 being rewritten to include all of the limitations of claim 14 and of intervening claim 17.

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Claims Rejected under 35 USC §102

In the above-mentioned Office Action, the Examiner said that claims 1, 3-8, 11, and 12 were rejected under 35 USC §102(b) as being anticipated by U.S. Pat. No. 6,416,467 to McMillin et al.

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Regarding claims 1 and 7, in this amendment, these claims are canceled.

Regarding claims 3-6, in this amendment, these claims have been rewritten to depend from claim 2, instead of from the canceled claim 1.

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Claim 6 is further amended to place requirements on the second handle portion that are similar to the requirements placed on the first handle portion by claim 1. Thus, the downwardly open slot of the second handle portion is additionally required to be J-shaped and to extend along a second lateral portion of the frame and inwardly along a second curved portion of the frame with a second side of the frame engaged within the downwardly open slot. Support for this change is found in the specification as originally filed in paragraph [0021].

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The Applicant respectfully submit that because dependent claims 3-6, as amended herein, merely add limitations to claim 2, which is understood to be patentable, having been rewritten as suggested by the Examiner and as described above, claims 3-6 are patentable under 35 USC §102(b) as not being anticipated by McMillin et al.

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Regarding claim 8, in this amendment, this claim has been rewritten in

independent form to include all of the limitations of the canceled claim 7, from which claim 8 originally depended. Additionally, claim 8 has been rewritten to include a requirement that the first and second lateral structures must be separately attached to separate portions of the frame. Support for this change is found in the specification as originally filed in paragraphs [0021] and [0024].

In the apparatus of McMillin et al., the lateral structures 92 are not separately attached to the frame, but are instead are attached to one another through a common adjuster device 94, which is turned to vary the spacing between the structures 82. This difference is significant because, the Applicant's apparatus, the lateral structures can be inserted and removed individually, with only one of the lateral structures being used if desired. For example, the sagging tissue to be held by the lateral structures may exist on only one side, or a procedure may require access to an area at one side that would otherwise be blocked by one of the lateral structure.

Therefore, the Applicant respectfully submits that McMillan et al. fails to anticipate the requirement of claim 8, as amended herein, for the first and second lateral structures to be separately attached to separations of the frame, and that claim 8, as amended herein, is patentable under 35 USC §102(b) as not being anticipated by McMillin et al.

Regarding claims 11 and 12, in this amendment, these claims have been rewritten to depend from claim 9, instead of from claim 8. The Applicant respectfully submit that because dependent claims 11 and 12, as amended herein, merely add limitations to claim 9, which is understood to be patentable, having been rewritten as suggested by the Examiner and as described above, claims 11 and 12 are patentable under 35 USC §102(b) as not being anticipated by McMillin et al.

Claims Rejected under 35 USC §103

In the above mentioned Office Action, the Examiner further said that claims 10, 13-17, and 19 were rejected under 35 USC §103(a) as being unpatentable over McMillin et al.

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Regarding claim 10, in this amendment, this claim has been rewritten to depend from claim 9, instead of from claim 8. The Applicant respectfully submit that because dependent claims 10, as amended herein, merely adds limitations to claim 9, which is understood to be patentable, having been rewritten as suggested by the Examiner and as described above, claim 10 is patentable under 35 USC §103(a) over McMillin et al.

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Regarding claim 13, the Applicant respectfully submits that McMillan et al. fails to teach or otherwise describe the requirement of this claim for a first lateral blade to be inserted within the vaginal opening *after* inserting and opening the opposed pair of blades. The design of the McMillin et al. device does not allow the separate insertion of lateral blades *after* the opposed pair of blades of the speculum is inserted and opened. Instead, McMillin et al. teaches against such a step, teaching instead in column 6, lines 22-40 that the speculum, including both longitudinal and latitudinal blades is inserted first, and that both sets of blades are then opened.

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This difference between the Applicant's invention and the prior art is significant, because the blades of the Applicant's invention can all be made relatively flat; there is no need to enclose the lateral blades within the opposed blades of the speculum when the opposed blades are closed against one another. Then, after the opposed blades are opened, the lateral blades are inserted, with the tissue being held in an open condition by the opposed blades, so that the lateral blades are easily inserted. Since the tissue is moved by being pushed outward, instead of by being wedged open, with attendant frictional forces, patient discomfort is

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minimized through the use of the Applicant's invention.

Therefore, the Applicant respectfully submits that claim 13 is patentable under 35 USC§103(a) over McMillin et al.

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Regarding claim 14, since this claim merely adds limitations including the insertion of another lateral blade within the vaginal opening *after* inserting and opening the opposed pair of blades, to the limitations of claim 13, the Applicant respectfully submits that, for reasons discussed above regarding claim 13, claim 14 is patentable under 35 USC§103(a) over McMillin et al.

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Regarding claim 15, the Applicant respectfully submits that McMillin et al. fails to teach or describe the requirement of this claim for the lateral blades to be removed from the vaginal opening before the opposed pair of blades are closed. McMillin et al. does not provide for the removal of the lateral blades with the speculum in place within the vagina, and the longitudinal blades cannot be closed with the lateral blades open. Therefore, and additionally because claim 15 merely adds these limitations to those of claims 13 and 14, which are believed to be patentable as described above, the Applicant respectfully submits that claim 15 is patentable under 35 USC§103(a) over McMillin et al.

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Regarding claim 16, the Applicant respectfully submits that McMillin et al. fails to teach or describe the requirements of this claim for the lateral blades to be inserted outwardly adjacent opposite sides of the open frame. As shown in FIGS. 1 and 5, the lateral blades are the innermost structures of McMillin et al., extending inwardly adjacent any frame structure. This difference between a version of the Applicant's invention and the device of McMillin et al. is significant because it allows the lateral blades of the Applicant's invention to be left in place, holding the vaginal tissue outward, as the opposing blades of the speculum are closed, so that the vaginal tissue cannot be pinched between these opposing

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blades as they are closed. Therefore, and additionally because claim 16 merely adds these limitations to those of claims 13 and 14, which are believed to be patentable as described above, the Applicant respectfully submits that claim 16 is patentable under 35 USC§103(a) over McMillin et al.

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Regarding claims 17 and 19, since these claims merely each add limitations to claims 13 and 14, which are believed to be patentable as described above, the Applicant respectfully submits that claims 17 and 19 are patentable under 35 USC§103(a) over McMillin et al.

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New Claims

Regarding claim 20, this claim is added within the amendment to add the additional limitations of claim 15, as originally presented, to those of claim 18. The Applicant respectfully submits that, for reasons described above regarding the rejection of claim 15, and additionally because this claim merely add limitations to claim 18, which is understood to be patentable, having been rewritten as suggested by the Examiner and as described above, claim 20 is patentable under 35 USC §103(a) over McMillin et al.

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Regarding claim 21, this claim is added within the amendment to add the additional limitations of claim 16, as originally presented, to those of claim 18. The Applicant respectfully submits that, for reasons described above regarding the rejection of claim 16, and additionally because this claim merely add limitations to claim 18, which is understood to be patentable, having been rewritten as suggested by the Examiner and as described above, claim 20 is patentable under 35 USC §103(a) over McMillin et al.

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Regarding claim 22, this claim is added within the amendment to add the additional limitations of claim 19, as originally presented, to those of claim 18. The Applicant respectfully submits that, because this claim merely add limitations

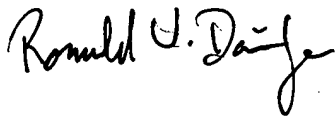
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to claim 18, which is understood to be patentable, having been rewritten as suggested by the Examiner and as described above, claim 20 is patentable under 35 USC §103(a) over McMillin et al.

5 **Conclusions**

The Applicant respectfully submits that the application, including claims 2-6 and 8-23 is now in condition for allowance, and that action, with reconsideration and reversal of all objections and rejections is earnestly requested.

10 Respectfully submitted,



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